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## Meaningful Use, Federal Regulation Top Priorities for Health IT in 2012

*The health care community as a whole in 2012 will remain focused on issues relevant to federal health care reform policies. But, the health information technology sector will continue in the coming year to address implementation of electronic health records in accordance with meaningful use criteria established by the Centers for Medicare & Medicaid Services and the corresponding technical standards from the Office of the National Coordinator—both stemming from 2009 legislation in the American Recovery and Reinvestment Act. As part of those efforts, health care and information technology industry experts told Bloomberg BNA, providers, health IT developers, policymakers, and the legal community will face ongoing and new challenges in the areas of IT interoperability, health information exchange sustainability, and liability issues raised by health IT adoption—or in some cases, failure to adopt. The health care provider community also can expect new health data privacy and security requirements in 2012 from the Department of Health and Human Services Office for Civil Rights, which will require changes to comply with new federal privacy and security standards at the same time states are enacting and enforcing state-based laws also aimed at protecting patients' health information.*

### Interoperability

Achieving interoperability among provider, hospital, and federal electronic health record systems will be both a major hurdle and the key to achieving sustainable adoption of electronic health record systems nationwide, health information industry experts told Bloomberg BNA.

As health care providers work to achieve ''meaningful use'' criteria set out by the Medicare and Medicaid EHR incentive programs over the course of 2012, business cases that provide a return on investment will rely on interoperable exchange of health information, Joel White, executive director of the Health IT Now Coalition, told Bloomberg BNA.

#### Top 10 Health IT Issues for 2012

The following are the top 10 health insurance issues to watch in 2012, according to Bloomberg BNA's *Health IT Law & Industry Report* Advisory Board.

1. Stage 2 meaningful use criteria and meaningful use attestation
2. Federal regulation of health IT
3. Interoperability
4. Mobile health applications
5. Congressional action affecting health IT and HIT funding
6. Privacy and security concerns and data breaches
7. Health information exchange progress
8. Litigation risks linked to EHR implementation and HIT use
9. Telehealth policies
10. ICD-10 implementation

''Fixing interoperability will help provide the data that can better make the business case for HIEs,'' White said. ''The lack of interoperability systemwide is impeding [the Health Information Technology for Economic and Clinical Health Act's] important objectives and may undermine future political support for the program.''

**HIE Sustainability.** While some regions have succeeded in developing sustainable models for health information exchange, others have ''failed miserably and expensively,'' Harry Greenspun, senior advisor for

health care transformation and technology at the Deloitte Center for Health Solutions, Washington, told Bloomberg BNA.

Some health systems are deploying their own HIEs as a way of connecting their hospitals and practices and often as a means to overcome internal interoperability challenges. This may help fuel growth of HIEs more broadly as more data becomes available, Greenspun said.

## Health Information Exchange

Meaningful use requirements for Stage 2 of the Medicare and Medicaid electronic health record incentive programs should promote health systems' successful models of HIE, and state governments and other entities should aid this effort by providing leadership and logical frameworks, while still allowing for flexibility in different models, Greenspun said.

''Experience has shown that one size does not fit all,'' he added.

CMS's proposed rule on Stage 2 of the meaningful use program is expected in January (*see previous article*).

White recommended that the Department of Health and Human Services add administrative transaction functionality to the Stage 2 meaningful use standards requirements, which would help run claims data through EHR systems that, in turn, could feed data to HIEs.

**''We continue to encourage ONC to adopt more robust standards for Stage 2 meaningful use that also assist providers in their workflows.''**

—Joel White, HIT Now Coalition

According to White, other strategies to strengthen the business case for health information exchange include:

- adding provider directories and credentialing services to HIEs' functions;
- using HIE clinical data streams for population health improvement and trend analysis; and
- using HIEs for care coordination efforts.

Stage 1 meaningful use criteria require providers and hospitals to test only their EHR systems' health information exchange capabilities, but do not require doctors and hospitals to use those capabilities.

## Meaningful Use

Last November, ahead of the anticipated release of the Stage 2 meaningful use rules in early 2012, HHS announced a delay of Stage 2 requirements for physicians and hospitals attempting to achieve Stage 1 in 2011 (*see previous article*).

The delay could signal an easing of Stage 2 requirements in light of the difficulty of implementing EHR systems and health information exchange capabilities, experts said.

''Given the announced delay to 2014, I think main changes will occur once there is more quality and outcome reporting [from Stage 1],'' Shannah Koss, president of Koss on Care LLC in Silver Spring, Md., told Bloomberg BNA.

James Oakes, principal with Health Care Information Consultants LLC in Baltimore, told Bloomberg BNA the delay in Stage 2 of the meaningful use program could mean that the second phase of the EHR incentive programs may never be fully implemented.

''As more hospitals try to qualify for meaningful use, they will find particular difficulty with the reporting requirements. Most systems simply don't support the [meaningful use] requirements,'' Oakes said.

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Due to both the delay in Stage 2 and the difficulties experienced by providers attempting to meet meaningful use of EHRs, a ''continued easing of the compliance bar [for meaningful use],'' should be expected in 2012, Mark Lutes, with Epstein Becker & Green PC in Washington, told Bloomberg BNA.

Overall, White predicted that most of the Stage 1 standards for meaningful use will at least be incrementally increased in Stage 2 of the incentive programs, and that many of the ''menu'' objectives will be moved to ''core'' requirements.

## Liability Concerns

Health IT industry experts said they also will be watching in 2012 the potential liability implications of EHR measurement errors or errors in data, experts said.

According to White, issues that could arise during the initial implementation of an EHR and as systems become widespread include:

- documentation gaps in the transition from paper to electronic records;
- incorrect or missing data because of errors by inexperienced system users; and
- errors because of ''bugs'' in systems.

White also said liability concerns could arise for physicians based on whether they act on clinical decision support recommendations because the decisions could raise questions of pathway adherence and bolster plaintiff cases. Similarly, White said, liability risks could be triggered if physicians or hospitals fail to adopt or use electronic technologies because not using the available IT could constitute a deviation from standards of care.

Furthermore, incomplete or missing information due to lack of interoperability among EHR systems could create gaps in knowledge and may lead to errors or

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poor decisions in diagnosis and treatment of a patient, White said.

**Safe Harbor Legislation.** White recommended that Congress encourage the adoption and use of health IT by developing safe harbors that allow for the continual improvement of patient safety without limiting patients' rights to legal recourse when they are harmed by medical malpractice.

Legislation was introduced Oct. 21 by Rep. Tom Marino (R-Pa.) to address liability concerns that have kept many hospitals and physicians from adopting and implementing electronic health record systems (*see previous article*).

Specifically, the Safeguarding Access for Every (SAFE) Medicare Patient Act (H.R. 3239) seeks to provide legal safe harbors to Medicare and Medicaid providers using certified electronic health records or other health information technology.

''This will reduce the doubt among some providers that liability risks outweigh the benefits of EHR and health information exchange adoption and promote increased willingness to fully integrate health IT into provider practices,'' White said.

## Congressional Action

In the coming year, lawmakers may look for the return on investment in health information technology and meaningful use, by cutting federal funding for health IT programs to fund other programs believed to more effective at cutting costs and increasing quality of care and efficiency, Lutes said.

According to Greenspun, the health IT industry will need to show steady progress in EHR adoption and early signs that implementing IT can, in fact, yield improvements in health care quality, safety, and cost.

**''Changes in health reform could reverberate in health IT and failure to show cost and quality improvement as a result of HIT investment could dial back HITECH.''**

—SHANNAH KOSS, CONSULTANT, KOSS ON CARE LLC

''If the future of incentive payments comes into question, that may have a very deleterious effect on adoption as providers and hospitals wonder if the payments will be there after they have made a significant investment,'' Greenspun said.

Meanwhile, states in 2012 will be faced with difficult budget decisions, which may impact their ability to support health IT adoption and information exchange, Greenspun added.

However, William Bernstein, chair of the health care division at Manatt, Phelps & Phillips LLP, said he expects 2012 to be a quiet year for health IT in Congress. ''Their focus has changed,'' he said.

Health information exchanges, health insurance exchanges, and Medicaid eligibility and enrollment systems could all combine in new initiatives, such as provider directories and data warehouses, he said.

## Federal Regulation

As the use of mobile medical applications grows and federal and state governments drive adoption of health information technologies, health care providers and technology developers increasingly are concerned about how federal regulators will seek to oversee EHRs, mobile health applications, and other health technologies.

In particular, industry experts are watching how the Food and Drug Administration will exercise its oversight authority to regulate mobile medical applications and mobile devices used for health related services.

Lutes said he expects the mobile device community and others with interest in mobile health technologies—including health care providers, patient advocacy groups, and health plans—to work with FDA to identify which mobile health applications pose ''sufficient risk to justify regulatory scrutiny.''

''I also expect that the provider community with a track record of successful customization of clinical software will want dialogue with FDA over where it might concentrate its review so as not to be needlessly in conflict with health information technology goals while advancing patient safety,'' Lutes added.

**Mobile Apps as Medical Devices.** White noted that FDA already has proposed regulating mobile medical applications as medical devices (*see previous article*) using the same approval process that was in place to regulate technologies as old as the now-obsolete floppy disk.

If mobile applications are regulated as medical devices, White explained, they could be subject to a new medical device tax under the Patient Protection and Affordable Care Act. The combined effect of increased regulation and new taxes for mobile medical applications could drive up costs and limit consumer accessibility, he cautioned.

''To address both the medical device tax and the additional regulator burden created by the guidance, mobile app developers will have little choice but to raise their prices,'' White said. ''It is also likely that small developers—businesses—would choose to write apps for other industries, drying up a creative pool that would leave only the largest companies to delivery on the mobile app promise. From a creatively standpoint, this is not good.''

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**Adverse Market Effects.** Koss likewise said increased regulation of health IT could have deleterious effects on the market.

''My hope is [FDA doesn't] wander further into this arena except for HIT that is truly an extension of a recognized medical device or they will undermine the emerging market,'' Koss said, noting that FDA has been

trying since the early 1990s to bring health IT under its umbrella.

Koss and White also said that of concern for the health IT industry is a recent Institute of Medicine recommendation (*see previous article*) that called for FDA to regulate health information technologies if the IT industry did not adequately address patient safety concerns raised by new technologies.

White said the regulatory uncertainty ''is a killer in nimble markets,'' and added that the additional layer of potential regulations for the health IT industry by the Federal Communications Commission and Federal Trade Commission could drive entrepreneurs to avoid the market altogether.

## Privacy and Data Security

When Congress passed the HITECH Act in 2009, as part of the larger American Recovery and Reinvestment Act, it signaled a renewed federal effort to protect the privacy and ensure the security of health care data.

Since then, the HHS Office for Civil Rights has issued a handful of proposed and interim final regulations that change and add to the requirements for entities covered by the Health Insurance Portability and Accountability Act.

Early in 2012, OCR is expected to release one final, omnibus HIPAA rule encompassing most of the HIPAA rulemaking it has undertaken in the past two years and covering a broad range of data privacy and security issues from data breach requirements to enforcement of requirements.

The omnibus rule will encompass four previously released proposed and interim final rules (*see previous article*). The bill will include:

- the final breach notification rule;
- the final HIPAA enforcement rule;
- the final rule implementing HIPAA privacy and security changes that were mandated in the HITECH Act; and
- a final rule implementing HIPAA changes mandated in the Genetic Information Nondiscrimination Act.

However, health care providers and the health IT industry are focused on more than federal HIPAA regulations. Privacy and data security mandates at the individual state levels also are among compliance concerns for organizations.

**Barriers in State Law.** In particular, state health data privacy laws have posed barriers for some health information exchange activities, and Bernstein said he expects state privacy issues to remain a significant concern for HIEs in 2012.

**''Federal law does not pre-empt state law, and state law measures are a barrier to exchanging health data.''**

—William Bernstein, attorney, Manatt, Phelps & Phillips LLP

''Federal law does not pre-empt state law, and state law measures are a barrier to exchanging health data,'' Bernstein said. ''It depends on which state, but the lack of a consensus on what appropriate privacy, consent, and secondary use should be remains a barrier.''

And, while states debate privacy mandates for exchanging data among entities within their jurisdictions, HIEs also face meeting multiple state requirements as they attempt to provide exchange capabilities for providers and health care entities across state lines.

''Progress is being made, but work on the ground level shows this is still highly debated among stakeholders,'' Bernstein said.

Protecting data privacy and security are considered key in protecting patients, but some industry watchers suggest that more should be done to also ensure the integrity of data used in the delivery of care.

''To-date, most attention has been focused on data security,'' Lutes said. ''It is my view that the consumer-patient harm of data security breaches is often overstated while the risks to patients from lack of data integrity are frequently underappreciated.''

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